3. 510(k) SUMMARY

K014253

MAR 2 6 2002

Date Prepared: 12/20/2001

Submitter:
Paradigm-Trex, LLC
10455 Pacific Center Court
San Diego, CA 92121-4339
Contact Person: Nikolai Tankovich, Ph.D. MD
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Device Trade Name: DermaChiller 4

Common Name: Skin refrigerant

Classification: Class II (21 CFR 878.4810)
Laser surgical instrument for use in general and plastic surgery and in dermatology.

Product Code: GEX

Performance Standards:
None established (as a medical device) under Section 514.

Description of Device:
The DermaChiller consists of a source of a refrigerant fluid controlled by an electronically operated solenoid delivery valve. The refrigerant fluid is sprayed in a controlled fashion onto a sapphire window, which is cooled and applied to skin.

Intended Use of the Device:
The DermaChiller 4 is intended as a skin-cooling device used to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort.

Substantial Equivalence Claim to:

1. CoolSpot – 510(k) Number K984110
2. Dynamic Cooling Device – 510(k) Number K001589
3. DermaCool– 510(k) Number K990417

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Paradigm Trex, LLC
Nikolai Tankovich, Ph.D., M.D.
Chief Executive Officer
10455 Pacific Center Court
San Diego, California 92121-4339

Re: K014253
Trade Name: DermaChiller 4
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 20, 2001
Received: December 26, 2001

Dear Dr. Tankovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

510(k) Number: K014253

Device Name: DermaChiller 4

Indications for Use: The DermaChiller 4 is intended as a skin-cooling device to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014253